Final Report to AHRQ for Project on:
"Health IT-Supported Process for Preventing and Managing Venous Thromboembolism (VTE)"

Title of Project:
Health IT-Supported Process for Preventing and Managing Venous Thromboembolism (VTE)

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Inclusive Dates of Project:
September 30, 2013-September 29, 2019

Federal Project Officer:
Chris Dymek

Acknowledgement of Agency Support:
This research was made possible by funding from the Agency for Healthcare Research and Quality (AHRQ), Grant Number: R01HS022086, Principal Investigator: Pascale Carayon.

Grant Award Number:
1R01HS022086-01A1

Structured Abstract
Purpose: The purpose of this project was to implement a sociotechnical systems approach to the development of a health IT-supported process for preventing and diagnosing VTE.
Scope: The project focused on cognitive and team work involved in VTE prevention (i.e. prophylaxis) and management (i.e. diagnosis and treatment).
Methods: Multiple data collection methods were used to examine: (1) clinician perceptions related to VTE prophylaxis and diagnosis; (2) cognitive analysis of clinician work involved in VTE prophylaxis and diagnosis; (3) human factors design process; and (4) team work analysis. The methods include interview, focus group, observation, and survey. The study was conducted in four hospitals in Pennsylvania and Wisconsin, and involved physicians, advanced practice providers, nurse and pharmacists in multiple hospital services and units, and emergency departments (ED).
Results: We developed two lists of design requirements for VTE prophylaxis and VTE diagnosis. In addition, we designed and evaluated a clinical decision support to support VTE diagnosis for ED patients; so called PE Dx. We demonstrated the value of using human factors methods and principles for designing the PE Dx CDS as its usability was higher on all dimensions as compared to a regularly used online CDS tool. Our results also show the need for a sociotechnical systems approach that uses multiple methods for collecting and analyzing data, involves multiple perspectives and disciplines, and considers health IT in the broader work system context.

Key Words: venous thromboembolism (VTE); pulmonary embolism (PE); health IT; clinical decision support (CDS); VTE prophylaxis; VTE diagnosis; role network analysis; sociotechnical systems; human factors and systems engineering.

1. INTRODUCTION

1.1 Purpose
This project had two specific aims. *Aim 1* was to evaluate the cognitive and team work involved in venous thromboembolism (VTE) prevention (i.e. prophylaxis) and diagnosis. *Aim 2* was to develop design requirements for a computerized clinical decision support (CDS) that supports cognitive and team work for preventing and diagnosing VTE. The aims address two separate clinical problems: (1) VTE prophylaxis among hospitalized patients, and (2) VTE diagnosis in the emergency department (ED). Information about methods and results are presented separately for each of the two clinical problems.

1.2 Scope
VTE remains a frequent but preventable complication for hospitalized patients that can lead to significant morbidity and mortality [1-3]. Comprised of deep vein thrombosis (DVT) and its complication pulmonary embolism (PE), an estimated 900,000 cases of VTE occur in the US each year [4]. Health information technology (IT) is used in VTE prevention interventions, such as electronic reminders and clinical decision support (CDS) for assessing VTE risk; however, empirical evidence shows that electronic alerts based on computerized VTE risk assessment have limited benefits [5-8]. Reasons may include restriction of these studies to high-risk patients, focus on prophylaxis with little or no consideration for VTE diagnosis and treatment, and lack of consideration for sociotechnical system factors in CDS design. Using a sociotechnical systems

approach that focuses on interactions between people and technology in the workplace [9], we developed design requirements for effective CDS for VTE prophylaxis, and VTE diagnosis.

2. METHODS

In the first part of the study, we focused on understanding the VTE prophylaxis process in the hospital, and the second part focused on the PE diagnosis process in the ED. These two VTE processes are very different. Therefore, in the rest of this report, we describe the parts separately.

2.1 VTE Prophylaxis

2.1.1 Study Design

This was an observational study using multiple data collection methods: interviews, focus groups, observations, surveys, and individual feedback sessions.

2.1.2 Setting

The VTE prophylaxis part of the study took place at four hospitals – GMC, GSACH, GWV, and UWHC: Geisinger Medical Center (GMC) in Danville, PA, Geisinger Shamokin Area Community Hospital (GSACH) in Coal Township, PA, Geisinger Wyoming Valley (GWV) in Wilkes-Barre, PA, and University of Wisconsin Hospitals and Clinics (UWHC) in Madison, WI. GMC is a 594-bed acute care teaching hospital with a Level 1 Trauma Center and serves as the main tertiary and quaternary care center for Central Pennsylvania. GSACH is a 70-bed acute hospital. GWV is a 283-bed acute care teaching hospital with a Level 2 Trauma Center. UWHC is a 609-bed acute care teaching hospital with a Level 1 Trauma Center. Different services were examined at – GMC: cardiology, critical care medicine, hospitalist, and emergency medicine; GSACH: hospitalist and internal medicine; GWV: critical care medicine, critical care surgery, hospitalist, and emergency medicine; and UWHC: critical care medicine, critical care surgery, hospitalist, and emergency medicine. Details about these services can be found in Table 1.

Table 1 – Characteristics of Participating Hospitals

Hospital/Service	Annual Adms*	# Beds
Geisinger Medical Center (GMC)		594
Cardiology	399	60
Critical Care Medicine	5548	24
Hospitalist	4314	58
Emergency Department	~45,000	35
Geisinger Shamokin Area Community Hospital (GSACH)		70
Hospitalist/Internal Medicine	3504	37
Geisinger Wyoming Valley (GWV)		283
Critical Care Medicine	3,303	60
Critical Care Surgery	491	46
Hospitalist	4,867	64
Emergency Department	53,500	32
University of Wisconsin Hospital and Clinics (UWHC)		609
Critical Care Medicine	943	24
Critical Care Surgery	1,255	24
Hospitalist	2,652	110
Emergency Department	55,764	34

* Admissions for fiscal year 2014

2.1.3 Sample

The participants in the study were physicians (attendings, fellows and residents), advanced practice providers (APPs), nurses and pharmacists (see table 2).

Table 2 – Participants in the Study Part on VTE Prophylaxis

Service	**Interviews (number/role; total hours, minutes)**	**Focus Groups (total hours, minutes)**	**Observations (total hours, minutes)**	**Surveys**
Geisinger Medical Center (GMC)				
Hospitalist	11 (3 attendings, 8 resident interviews with 10 participants; 6h 36m)	1 (7 IM/peds residents; 1h 35m)	13 patient rounds (4 h 30m)	32 providers*, 71 nurses
Critical Care Medicine	6 (5 CCM/1 CCS attendings; 4h 18m)	n/a	22 patient rounds (6h 30 m)	18 providers, 125 nurses
Cardiology	3 (attendings; 1h 44m)	n/a	26 patient rounds (7h 40m)	38 providers, 118 nurses
Pharmacy	n/a	n/a	n/a	29 pharmacists
Geisinger Shamokin Area Community Hospital (GSACH)				
Hospitalist	1 (attending; 27m)	n/a	n/a	n/a
Internal Medicine	2 (attendings; 1h 24m)	n/a	n/a	n/a
Geisinger Wyoming Valley (GWV)				
Hospitalist	4 (3 attendings, 1 APP; 1h 40m)	n/a	21 patient rounds (1h 35m)	31 providers, 89 nurses
Critical Care Medicine	2 (attendings; 1h 33m)	n/a	9 patient rounds (2h 30m)	13 providers, 78 nurses
Critical Care Surgery	1 (attending & APP paired; 30m)	n/a	n/a	n/a
Pharmacy	n/a	n/a	n/a	27 pharmacists
University of Wisconsin Hospitals and Clinics (UWHC)				
Hospitalist	9 (7 attendings, 2 residents; 7h 17m)	n/a	61 patient rounds (4h 32m)	17 providers, 77 nurses
Critical Care Medicine	3 (attendings; 2h 57m)	n/a	62 patient rounds (20h 39m)	16 providers, 50 nurses
Critical Care Surgery	7 (4 attendings, 1 fellow, 2 residents; 5h 39m)	n/a	56 patient rounds (18h 16m)	12 providers, 50 nurses
Pharmacy	n/a	n/a	n/a	74 pharmacists
Total	52 participants (35 attending physicians, 1 fellow, 14 residents, 2 APP), in total 34 h 5 m)	7 participants, 1 h 35m	270- patient rounds, 66 h 12 m	977 respondents

* Provider = physicians and advanced practice providers (APPs)

2.1.4. Data Collection

2.1.4.1 Interviews and Focus Group

We conducted interviews with attending physicians, residents and APP from eleven services at four hospitals. The goal of the interviews was to identify the work system barriers and facilitators the physicians/APPs encounter when determining the need to place or continue a VTE prophylaxis order at various stages in the hospital stay: on admission, throughout the continued stay, when prophylaxis requires interruption, when re-initiation of prophylaxis should begin after

interruption, when initiation of prophylaxis should occur because it was not ordered on admission, and on patient transfer to the respective service. For one service (internal medicine at GMC), we conducted a focus group of seven residents and captured the same information collectively. We also asked participants about possible solutions to improve the VTE prophylaxis process. Interviews and the focus group were audio recorded and transcribed for data analysis.

2.1.4.2 Observations

We conducted observations for eight services at three hospitals. The purpose of the observations was to complement the interviews and focus group data. Information collected included: members on rounding team, computer usage, physical environment in which rounds occurred (bedside, hallway, conference room), duration of rounds, any VTE-specific health IT used (e.g., risk assessment tool CDS), and whether any discussion regarding prophylaxis occurred.

2.1.4.3 Survey

We used a combination of survey administration methods (paper-and-pencil and web-based) to collect data in three hospitals (GMC, GWV, and UW). Researchers distributed the surveys during meetings to physicians. Whenever possible physicians completed the survey during the meeting and returned the completed survey to the researcher at that time. If it was not possible to return the completed surveys immediately, the physicians were asked to return the completed surveys to administrative assistants in their respective services. On a regular basis, researchers collected the surveys from the assistants. The response rate for physicians was 90%. Researchers met with nurse managers on different units, explained the goal of the study and asked for their help with survey distribution. The nurse managers then distributed the surveys to nurses. On a regular basis, researchers visited the units to collect the completed surveys. On one unit, we used a combination of a paper survey and a web-based survey. Using these procedures, the response rate for nurses was 86%. Data collection among pharmacists (and some of the nurses at one hospital) was conducted with a web-based survey. The procedure consisted of an introductory e-mail by leadership followed by an invitation from the study PI to take part in the survey. The initial invitation to participate was followed by three reminders. The response rate using this procedure was 68% for pharmacists and 58% for nurses in the unit that was offered a combination of a paper and web-based survey. The overall response rate in the study was 84%.

2.1.5 Data Collection Instruments

2.1.5.1 Interview Guide

The prophylaxis interview guide contains questions about the process of VTE prophylaxis, information needed to review, key people involved in the process, and possible (health IT) solutions to improve the process. The interview guide is available at: https://cqpi.wisc.edu/wp-content/uploads/sites/599/2016/07/VTE-prophylaxis-VTE-Interview-Guide.pdf

2.1.5.2 Observation Instrument

The observation instrument allowed us to keep track of different rounding activities, key personnel, and the configuration of the team. The observation tool is available at: http://cqpi.wisc.edu/wp-uploads/2016/07/Multidisciplinary_Rounds_Observation_Tool.pdf

2.1.5.3 Survey

The VTE prophylaxis survey was adapted from Lloyd et al. [10]. The survey has 6 parts: (1) respondent information, (2) perceptions of VTE prophylaxis, (3) barriers to VTE prophylaxis, (4) perceived effectiveness of interventions to improve VTE prophylaxis, (5) guestimates of prophylaxis, and (6) role and responsibilities in the prophylaxis process. The versions for the different clinician groups are available at:

- Physician: http://cqpi.wisc.edu/wp-uploads/2016/07/VTE-Prophylaxis-Survey-RiskAsssessmentTool-Physicians-Final.pdf
- Nurse: http://cqpi.wisc.edu/wp-uploads/2016/07/VTE-Prophylaxis-SURVEY-Nurses-FINAL.pdf
- Pharmacist: http://cqpi.wisc.edu/wp-uploads/2016/07/VTE-Prophylaxis-Survey-Pharmacists-Final.pdf

2.1.6 Data Analyses

2.1.6.1 Interviews and Focus Group

Transcripts for the interviews and focus group were uploaded to Dedoose® web-based qualitative data analysis software. Relevant excerpts were coded and subsequently summarized by VTE prophylaxis stage for each participating service at each hospital. Each summary included a description of the VTE prophylaxis activity(ies), role(s) involved, tool(s)/technology(ies) being used (if any were used) and any location-, organization- or service-specific information relevant to the summary. Once all interviews were summarized, the descriptive information was transferred to a role network analysis, using Lucidchart® on-line diagramming software, one for each of the six stages of VTE prophylaxis, for each service, at each hospital.

Data from the role network analyses were then entered in an Excel spreadsheet for later analysis of EHR use for individual activities and team interactions as well as to calculate social network analysis (SNA) measures of reciprocity, centrality, and number of roles, individual activities and team interactions for high- and low-complexity stages of VTE prophylaxis. For more information on the SNA analysis, see Salwei et al. [13].

2.1.6.2 Survey Analysis

A total of 1,187 surveys were distributed in the four hospitals with 1,009 surveys returned, for an overall response rate of 84%. We combined all data in a single SPSS© (version 25.0) database that allows us to conduct comparative analyses. For more information on the survey data analysis, see Hoonakker et al. [14].

2.1.6.3 Case Study Analyses

We combined the data collected with mixed methods on the different services in the hospitals in case summary reports, and produced a total of 11 case study reports. We compared the different cases and noted similarities and differences. The results of the cross-case analysis and the analysis of potential solutions to improve the VTE prophylaxis process resulted in a list of sociotechnical system (STS) design requirements for a VTE prophylaxis CDS. The list of STS design requirements was shared with experts in individual and group sessions. Based on the feedback received, we finalized the list of STS design requirements.

2.2 VTE Diagnosis

2.2.1 Study Design

This part of the study was partly observational and partly quasi-experimental. We used an observational study with mixed data collection methods (interviews and focus groups) to understand the VTE diagnostic process. We used a quasi-experimental study to compare our human factors-based CDS (so called PE Dx) with an existing online CDS for PE (MD Calc).

2.2.2 Setting

Research activities for this part of the study took place in the Emergency Departments in three hospitals: GMC, GWV and UWHC (see table 1).

2.2.3 Sample

ED attending physicians, residents (Yr. 1-4), APPs and nurses took part in the study. Table 3 summarizes the sample and the data collection activities. To test the CDS, we conducted a quasi-experimental study that involved 32 physicians.

Table 3 – Participants in the Study Part on VTE Diagnosis

EDs	Interviews	Focus groups	PE Dx experiment
Geisinger Medical Center (GMC)	7 (4 attendings, 3 residents; 5h 18m)	n/a	n/a
Geisinger Wyoming Valley (GWV)	4 (2 attendings, 2 nurses; 1h 46m)	n/a	n/a
University of Wisconsin Hospitals and Clinics (UWHC)	12 (6 attendings, 3 residents, 1 APP, 2 nurses; 10h 55m)	2 (2 participants each)	32 (8 each: attending, yr. 1, 2 & 3 residents)
Total	23 participants (12 attendings, 6 residents, 1 APP, and 4 nurses (17 h 59 m)	4 participants	32 participants 8 Attendings 8 Yr. 1 Residents 8 Yr. 2 Residents 8 Yr. 3 Residents

2.2.4 Data Collection

This part of the study consisted of three stages. In the initial stage, we collected data, mainly through interviews and focus groups, to better understand the VTE diagnostic process. During the second stage, we conducted a large literature review on the scope and impact of CDS in the ED. More details about this part of the study can be found in the paper by Patterson et al. [15]. The third part consisted of comparing usability (efficiency, effectiveness and satisfaction) of PE Dx with an existing online CDS. Details of that part of the study can be found in the paper by Carayon et al. [16].

In the initial data collection, we talked to 27 participants in 3 EDs during 23 face-to-face interviews and 2 focus groups. This data collection lasted in total nearly 18 hours. Based on the information that we collected during the initial phase of the study, we formulated design requirements for a CDS to support the PE diagnostic process. We also conducted a large literature review of scope and impact of CDS in the ED. We identified a total of 2,558 potential studies; 42 studies met inclusion criteria. Common targets for CDS intervention included medication and radiology ordering practices, as well as more comprehensive systems supporting diagnosis and treatment for specific disease entities. The majority of studies (83%) reported positive effects on measures of interest. Most studies (76%) employed a pre-post experimental design, with only three (7%) randomized control trials [15].

We developed design requirements during several design sessions with the goal to design a CDS to support the PE diagnostic process. We conducted 9 design sessions in which the design team consisting of 6 human factors experts and 2 clinicians discussed advantages and disadvantages of several design solutions for PE Dx. The 9 design sessions lasted 13.5 hours. More information about the design sessions can be found in Hoonakker et al. [17].

Thirty-two emergency physicians participated in the quasi-experimental study of PE Dx. In the first session, they followed instructions using an Internet-based CDS (MD Calc for Wells' and PERC) that calculates the risk of PE. After using the CDS, the participants indicated the clinical pathway they would order (order nothing, order a D-dimer test, or order a CTA scan). In the second session, participants followed similar instructions, but used the CDS designed by the research team that was integrated in the EHR (PE Dx). Details about the study can be found in Carayon et al. [16] and Salwei et al. [18].

2.2.5 Data Collection Instruments

2.2.5.1 Interviews

We used a modified Critical Decision Method interview technique [19], integrating the work system model [9] to identify work system barriers and facilitators to the cognitive process of making a diagnosis of PE or DVT. Each interview included 2-3 human factors researchers, one conducting the interview and the other(s) serving as logistician. Using a semi-structured interview guide, the researcher asked the clinician to describe his/her activities related to VTE diagnosis. All interviews were audio recorded and transcribed by a professional transcription service. The interview guide can be found at: https://cqpi.wiscweb.wisc.edu/wp-content/uploads/sites/599/2016/08/CDM-combined-DVT-PE-dx-VTE-Interview-Guide-5-12-16.pdf

2.2.5.2 Experiment of the Clinical Decision Support (PE Dx CDS)

We used Camtasia Studio 8® screen-capture software to record participants' navigation through the EHR and to collect data on use to accomplish the goals (i.e. the five scenarios). Participants completed a paper survey after each of the 5 scenarios within a session on which they indicated (1) the appropriate clinical pathway for a given scenario, and (2) their confidence in that decision on a 10 cm visual analogue scale. After each scenario in a session, participants completed an electronic survey. The after-scenario survey (ASS) consisted of 3 questions about their satisfaction with the task that they just performed. The ASS was adapted from the After-Scenario Questionnaire [20]. Participants also responded to questions about the workload experienced for the scenario using the NASA TLX [21]. At the end of each session participants filled out the Computer Usability System Questionnaire (CUSQ) [22]. At the end of session 2 (with PE Dx), participants indicated their preference for the CDS tool. Details about the study procedures can be found in Carayon et al. [16].

2.2.6 Data Analysis

2.2.6.1 Analysis of Interview and Focus Group Data

Transcripts for the interviews and focus group were uploaded to Dedoose® web-based qualitative data analysis software. Relevant excerpts were coded and subsequently summarized by VTE prophylaxis stage for each participating service at each hospital.

2.2.6.2 Experiment of PE Dx

We used data collected with the screen-capture software and the survey to assess differences in usability between the two CDS; this was done with a three-level empirical Bayesian model to obtain the estimates of marginal means.

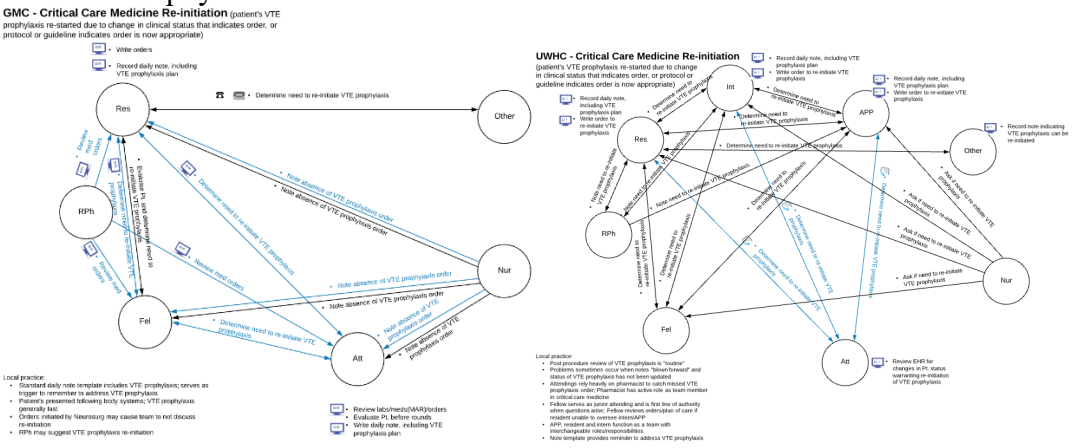
3. RESULTS

3.1 VTE Prophylaxis for Hospitalized patients

3.1.1 Role Network Analysis of VTE Prophylaxis

We created 61 role network analyses depicting roles, activities and interactions as well as technology use associated with VTE prophylaxis by or between team members for the eleven services at the 4 hospitals (all six VTE prophylaxis stages were not relevant for all the services). Figure 1 provides a comparison of the VTE prophylaxis in the re-initiation stage for critical care medicine services at two hospitals. Differences in the number of roles and associated interactions, amount of outside versus during rounds interaction, extent of EHR use during team interactions, and number of individual activities can be visually identified.

Figure 1 – VTE Prophylaxis Re-initiation in Two Critical Care Medicine Services



Data from the role networks produce information on individual activities, team interactions, and EHR use. Across all services at all hospitals, there were 273 individual activities performed and 533 team interactions. There were four categories of individual activities: 1) assess for VTE risk/contraindication to VTE prophylaxis, 2) monitor EHR, 3) record notes, and 4) write orders. We identified six categories of team interactions: 1) decide care plan, 2) discuss care plan, 3) share patient information, 4) remind team and monitor care plan, 5) communicate to act on follow-up, and 6) interact with patient. The extent of EHR use across these categories of activities and interactions varies with considerably more EHR use during individual activities (see figures 2 and 3).

Figure 2 – EHR Use During Individual Activities of VTE Prophylaxis

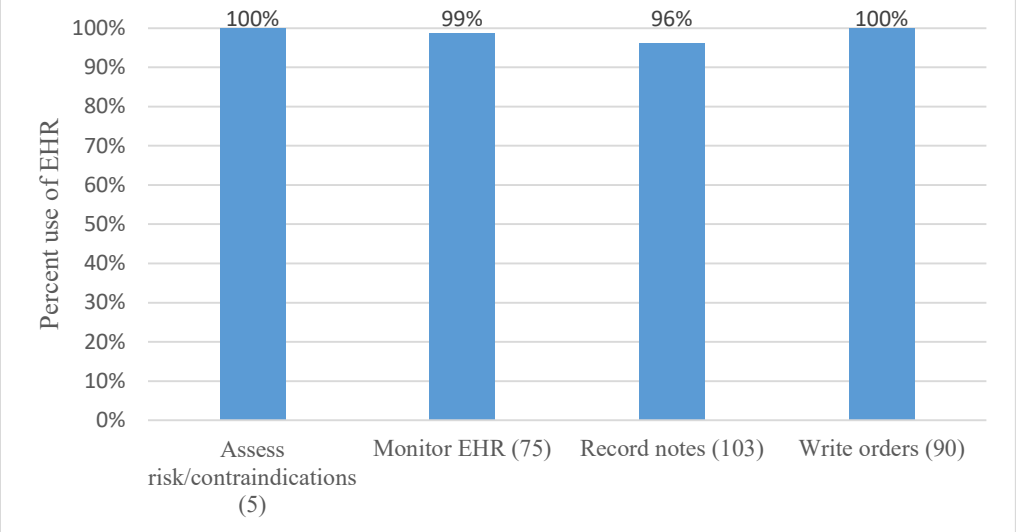
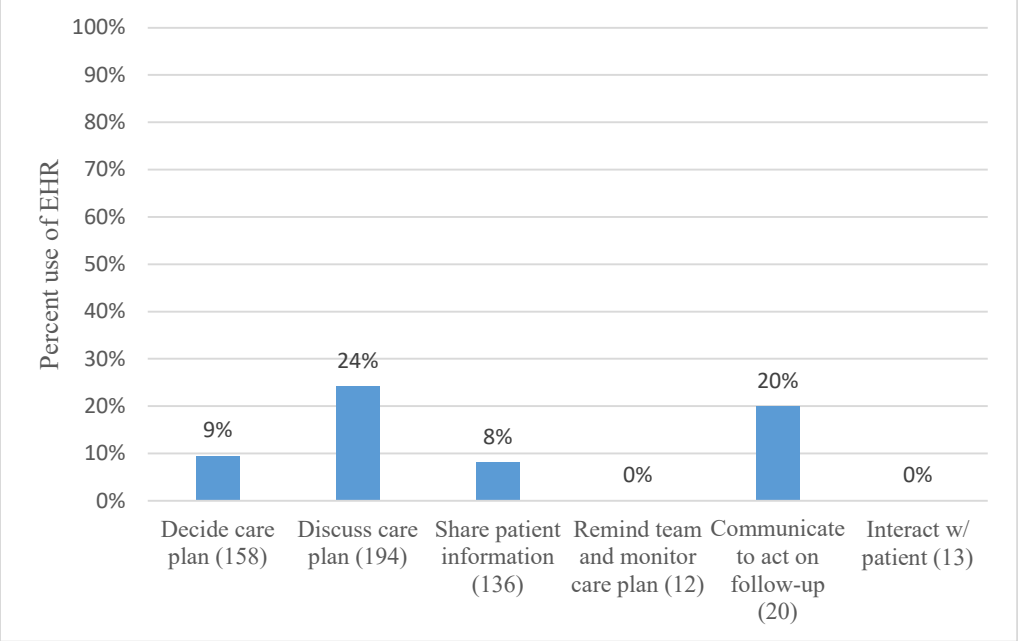


Figure 3 – EHR Use During Team Interactions of VTE Prophylaxis



We used data from the role network analysis to calculate social network analysis measures and compare low-complexity (i.e., admission and transfer) and high-complexity (interruption, re-initiation, and initiation) stages of VTE prophylaxis. Results show that high-complexity stages of VTE prophylaxis are associated with more roles, team interactions and activities or greater reciprocity for all services but Cardiology at Hospital A [13].

3.1.2. Results of the VTE Prophylaxis Survey

3.1.2.1 Perceptions of VTE Prophylaxis

Overall, respondents thought that VTE prophylaxis was *very important* (88%), *very effective* 53%), and *very safe* (55%). Fifty-three percent of respondents thought VTE prophylaxis was appropriately utilized, 20% thought it was (somewhat) under—utilized and 26% thought it was (somewhat) over-utilized. There is only one statistically significant difference between the three clinician groups (nurses, physicians and pharmacists) with regard to utilization of VTE prophylaxis: physicians thought that overall, VTE prophylaxis was slightly under-utilized and pharmacists and nurses thought that it was (slightly) over-utilized.

3.1.2.2 Barriers to VTE Prophylaxis

Results show that the largest barrier to VTE prophylaxis is patient discomfort from subcutaneous injections. The second most important perceived barrier to prophylaxis is clinician's concerns about bleeding, and the third lack of time to consider prophylaxis in every patient. There are differences between the three clinician groups. For nurses, patient discomfort is the largest barrier (23% perceive this as a major barrier, but only 9% of physicians and 6% of pharmacists). Physicians (9%) consider increased bleeding risk as the largest barrier (19% of pharmacists and 5% of nurses). Pharmacists see more barriers to VTE prophylaxis than physicians or nurses, and are more concerned about lack of clear indications (16%) and contra-indications (12%) for VTE prophylaxis, and lack of physician agreement with the current guidelines (16%).

3.1.2.3 Perceived Effectiveness of Interventions to Improve VTE Prophylaxis

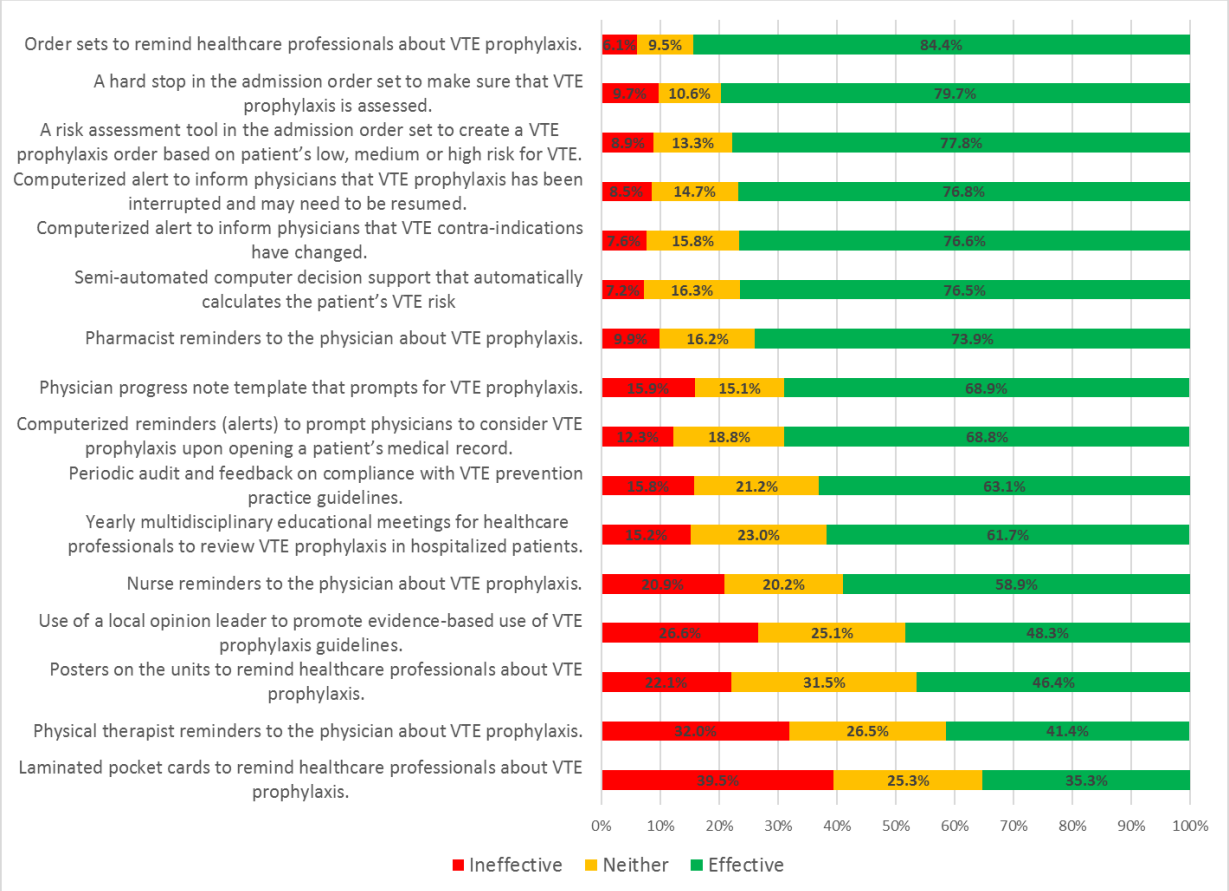


Figure 4 – Perceived Effectiveness of Interventions to Improve VTE Prophylaxis

3.1.2.4 Roles and Responsibilities in the VTE Prophylaxis Process

Survey participants answered three questions about roles and responsibilities in the VTE prophylaxis process. For example, respondents were asked: "Which clinician group (physician, fellow, physician assistant or nurse practitioner, resident, consultant physician, nurse, pharmacists or physical therapist) is best able to ensure that VTE prophylaxis is ordered"? Results show that –according to respondents- no particular clinician group was perceived to be best able to perform a specific task. Instead, respondents often chose their own profession to be best able to perform a certain task. For example, nearly half of the attending physicians (48%) indicated that they were the clinician group best able to provide daily assessment of patient need for prophylaxis, but 59% of residents (35% of APPs, 28% of pharmacists, and 29% of nurses) thought that they were the clinicians best able to perform the same task. Results showed that no single clinician group was perceived to be best able to perform a certain VTE prophylaxis task. Uncertainty and ambiguity about VTE prophylaxis tasks make the process complicated.

3.1.3 Cross-Case Study Analysis

We created 11 case study reports, one for each of the services that participated in this study, by compiling contextual information and survey, observation, interview, and role network data. The objective of this "data synthesis and analysis" was to produce sociotechnical design requirements for clinical decision support.

3.1.4 Design Requirements for VTE Prophylaxis

Through a divergent/convergent process, we developed a set of design requirements for VTE prophylaxis CDS (see table 4).

Table 4 – Design Requirements for VTE Prophylaxis CDS

Categories	Design Requirements	Examples
Patient journey	Track current VTE prophylaxis orders throughout the patient hospitalization.	VTE prophylaxis order, who placed the order, if ordered dose administered (or not), and doses patient refused
	Provide real time status of risks/benefits and contraindications to VTE prophylaxis (reflecting change in bleed/clot risk) that affect decision making.	Daily status board of relevant information that conveys change in bleed/clot risk Hover over
	Provide relevant real time information related to VTE prophylaxis that conveys the patient journey (i.e. stage of prophylaxis & physical location) and clinical changes (e.g., patient status, lab results, orders) over time.	Dashboard of hospitalization to date showing relevant information trended over the stay
	Provide information on planned procedures that suggests interruption of VTE prophylaxis and re-initiation post-procedure.	Procedure-specific risk assessment in order set Information displaying period during which to hold dose and time of procedure (to know when to begin to hold/stop dose)
Clinical appropriateness (decision-making)	Ensure VTE prophylaxis order is clinically indicated based on organization's best *(evidence-based?)* practice while also being aware of differences by proceduralist.	Standard order sets -- automatically generated when corresponding order entered

Categories	Design Requirements	Examples
	Support easy/timely discussion and access to specialists, especially proceduralists, who also provide feedback on appropriateness of interruption or re-initiation.	In-person AND electronic communication
	Consider use of chemical and/or mechanical prophylaxis.	Both forms of prophylaxis in order set
Physician teamwork	Support ongoing, distributed communication, including shared decision making, between providers regarding VTE prophylaxis decisions.	Instant Messaging in EHR
	Establish consensus by including multiple medical and surgical specialties in determining standards that drive decisions regarding interruption and re-initiation of VTE prophylaxis.	Standard order sets -- automatically generated when corresponding order entered
Role clarity	Consider team configurations and identify who is responsible for various aspects of VTE prophylaxis -- education (e.g., clinician -- esp. clinician-in-training; patient), ordering, monitoring.	Responsible party at standard time each day -- e.g. morning rounds
Built-in redundancy or error recovery	Create a "second set of eyes" (e.g., people and/or automation) to monitor for and suggest interruption or re-initiation of VTE prophylaxis.	Order read-back, telehealth Defined roles
Structure for rounds and shift change	Provide structure for team discussion that facilitates situation awareness -- either during bedside or tabletop rounds -- to ensure need for interruption or re-initiation is discussed.	Checklists, EHR reminders
	Consider team size to support decision maker who may not have another provider present when determining VTE prophylaxis interruption or re-initiation.	Educational support (e.g., hover over, link) to clinician
	Provide structure during handoff so consideration for interrupting or re-initiating VTE prophylaxis is addressed.	Checklist
Organizational culture	Ensure open/transparent culture where anyone (including physicians-in-training, pharmacists and nurses) can suggest interrupting or re-initiating VTE prophylaxis.	Pharmacist as team member
Workload	Ensure any new process is efficient and effective (cannot add workload).	
Technology access	Support access to information through readily available technology, especially when space is spread.	Various platforms -- tablet, laptop, smart phone to promote ease of access
	Use technology that is mobile and fits with the environment.	Large screen for all to see
Environment	Provide enough and appropriate space for all team members.	
Education of nurses and physicians	Educate team members regarding VTE prophylaxis interruption and re-initiation based on agreed upon organization standards; also educate on team training.	

Categories	Design Requirements	Examples
Education of patients	Educate patients on importance of VTE prophylaxis (including risks and benefits and their role) and engage them as team members in monitoring order and administration of VTE prophylaxis.	Patient as team member, including information they need
Unit-level monitoring	Provide real time dashboard for unit at patient and unit levels denoting status of appropriate VTE prophylaxis.	Dashboard, check-lists, percent of pts on VTE prophylaxis
	Provide feedback on impact of VTE prophylaxis ordering / adherence over time.	Report reflecting bleeding/clotting incidence and VTE prophylaxis use over time

3.2 VTE Diagnosis in the ED

3.2.1 Cognitive Analysis and Role Network Analysis of VTE diagnosis

Results of our analysis showed that physicians need to find information for PE diagnosis in 9 different places in the EHR that they use and that they can use up to 26 different sequences to access the information. On average, they use 3.3 clicks and scrolls per sequence [23]. The highly fragmented information in the EHR was an important reason to design a CDS that made it relatively easy to access all information needed.

3.2.2 Human Factors Design and Evaluation of CDS for PE Diagnosis

Based on information gathered in the cognitive analysis and role network analysis phases and during the design sessions, we created a CDS for pulmonary embolism diagnosis (PE Dx). For a description of the design process, see Hoonakker et al. [17]. PE Dx makes use of several human factors design principles to improve workflow, usability and eventually, medical decision making of physicians (see table 5). For a detailed description, see Carayon et al. [16]. For example, PE Dx auto-populates vital signs, carries over information entered in the first part of the decision-making process (Wells' criteria) to the second part to rule out a PE (PERC criteria). PE DX suggests the best, evidence-based follow-up (e.g. stop PE workout, order D-dimer, order CAT scan) and PE DX allows to (automatically) copy and paste the results of the decision making rules into the physician's notes.

Table 5 – Design Requirements for PE CDS

Human Factors Design Principles	Implementation in PE-Dx CDS
Automation of information acquisition	Auto-population of some Wells' and PERC criteria using EHR data.
Automation of information analysis	Computation of Wells' score by CDS.
Support of decision selection	Provision of recommendation for next step in diagnostic pathway, e.g. doing nothing, ordering D-dimer, ordering CTA scan.
Explicit control/flexibility	Ability to change values for Wells' criteria – e.g. possible to change heart rate/pulse – to support physician clinical judgment and unique patient situations.
Minimization of workload	Minimization of data entry; e.g. data for Wells' automatically populated in PERC. PERC appears only if Wells' score is low. No need to enter data for all PERC criteria once any PERC criterion is positive. Automatic generation of text for documentation of medical decision-making.

Human Factors Design Principles	Implementation in PE-Dx CDS
Consistency	Consistency with how information is presented in other parts of the EHR; e.g. use of Yes/No toggle. Consistency with how Wells' and PERC criteria are listed on MDCalc website that is routinely used by physicians.
Chunking/grouping	Wells' criteria and PERC rule presented separately. Placement of CDS in ED navigator of EHR.
Visibility	Indication of points/weights assigned to each Wells' criterion to make it clear/transparent how Wells' score is computed.
Error prevention	In order to avoid documenting wrong Wells' score, all Wells' criteria must be addressed.

Results of our quasi-experimental study showed that, compared to an online CDS (MD Calc), PE Dx resulted in physicians making more appropriate decisions (94% with PE Dx vs 84% with MD Calc, $p<0.01$), performing their tasks faster ($p<0.001$), with less workload ($p<0.001$) and with more satisfaction ($p<0.001$) (see table 6).

Table 6 – Impact of PE Dx CDS on Usability (mean score [standard deviation], effect size [95% confidence interval] and p-value)

Dependent Variables	MDCalc	PE-Dx CDS	Effect Size (CI)	p-value
Effectiveness				
% appropriate decision	83.75% [0.37]	94.38% [0.23]	0.35[a] [0.03, 0.17]	p<0.01
Confidence level*	80.21 [18.94]	82.71 [18.21]	0.13[b] [-0.05, 0.31]	p=0.14
Efficiency				
Time per scenario (in seconds)	117.37 [38.91]	95.84 [95.84]	-0.55[b] [-0.71, -0.38]	p<0.001
Number of clicks per scenario	16.49 [4.82]	17.90 [3.91]	0.29[b] [0.09, 0.48]	p<0.01
Number of scrolls per scenario	7.47 [2.92]	6.31 [2.50]	-0.39[b] [-0.57, -0.21]	p<0.001
Number of navigation elements per scenario	15.53 [5.01]	10.23 [2.74]	-1.05[b] [-1.26, -0.83]	p<.001
Perceived workload**	4.45 [1.53]	3.64 [1.78]	-0.52[b] [-0.68, -0.37]	p<0.001
*Satisfaction****				
CUSQ – overall satisfaction	5.62 [0.94]	6.18 [0.66]	0.58[b] [0.18, 0.98]	p<0.001
CUSQ – system usefulness	5.65 [0.95]	6.26 [0.67]	0.62[b] [0.19, 1.05]	p<0.01
CUSQ – information quality	5.73 [0.98]	6.17 [0.73]	0.43[b] [0.03, 0.83]	p<0.05
CUSQ – interface quality	5.48 [1.15]	6.02 [0.86]	0.45[b] [0.07, 0.84]	p<0.05

* One question: 0 (no confidence) to 100 (very high confidence) .
** Scale: 1 (low) to 10 (high) [NASA TLX Workload].
*** Response categories: 1 (strongly disagree) to 7 (strongly agree) [CUSQ=Computer System Usability Questionnaire].
[a] = Cohen (h) effect size based on the inverse sine of the square root of the proportional values.
[b] = Becker adjusted effect size for repeated measures.

4. DISCUSSION

4.1 Conclusion and Significance

4.1.1 VTE Prophylaxis Process

Results showed that VTE prophylaxis is not a single task that is performed at hospital admission. VTE prophylaxis is a process that involves many different people and roles at various stages of the hospitalization. The process includes the following stages: VTE prophylaxis initialization at admission (vs. non-initialization because of a contra-indication such as bleeding); interruption, for example, because of a procedure such as surgery; and re-initialization. The VTE prophylaxis process is less complex if the patient is prescribed VTE prophylaxis upon admission. However, the process becomes rapidly more complex when VTE prophylaxis is initially not prescribed because of a contra-indication, or when prophylaxis is interrupted, for example because of a procedure, and needs to be re-initialized after the procedure.

Results from the survey showed that VTE prophylaxis is perceived as important, safe, and effective. The greatest perceived barriers to VTE prophylaxis are: the patient's risk of increased bleeding and patient discomfort from the subcutaneous injections. Technology solutions, such as a computerized alert to inform physicians that VTE prophylaxis has been interrupted, were identified to be most effective in ensuring appropriate VTE prophylaxis. There was wide variation in responses to questions on roles regarding providing daily assessment of patient need for VTE prophylaxis, ensuring placement of VTE prophylaxis order and ensuring adherence of VTE prophylaxis treatment. These survey results demonstrate significant role ambiguity regarding VTE prophylaxis activities, including ordering, administration and monitoring. In all hospitals, nurses are more likely to be responsible for ensuring adherence to VTE prophylaxis. In non-teaching hospitals, the attending physician is most likely considered responsible for ensuring that VTE prophylaxis is ordered and for daily assessment of VTE prophylaxis; in teaching hospitals, these activities are most likely considered the responsibility of residents.

Our results showed that the design of a health information technology to support VTE prophylaxis for hospitalized patients needs to take the following aspects into account:

- The health IT needs to be designed to support the whole process (instead of a single task) throughout the patient hospitalization.
- The health IT needs to be designed to support both low- (admission and transfer) and high-complexity (interruption, initiation and re-initiation) stages of the VTE prophylaxis process.
- The health IT needs to be designed to support teamwork (instead of a single user); clear roles need to be assigned to different team members to avoid role ambiguity and role confusion.
- The health IT needs to be "smart", which means for example, a smart risk assessment tool that auto-populates as much information as possible, or a computerized alert indicating that VTE prophylaxis has been interrupted and needs to be resumed.

4.1.2 PE Diagnosis

Based on our data and multiple analyses from various perspectives, we designed a human factors-based CDS to support the PE diagnosis process (PE Dx). The design of the PE Dx involved several stages, including a heuristic usability evaluation. A total of 32 physicians (8

attending physicians and 24 residents) participated in a quasi-experimental study to evaluate the usability of PE Dx. Results showed that PE Dx was more effective and efficient and that users were more satisfied with PE Dx as compared to the online CDS (MD Calc). The design of PE Dx was based on multiple human factors methods and design principles. The results of the experiment showed the benefits of using human factors methods and principles when designing health information technology. The following human factors design principles were key to the high usability of PE Dx, i.e. a CDS to support the PE diagnostic process in the ED:

- Health IT should be designed to use data already available in the EHR and present them in an integrated manner; this will avoid the data fragmentation in the EHR that many physicians find frustrating.
- Health IT should minimize the work and workload associated with its use and provide easy-to-implement recommendations; therefore, providing important benefits to busy clinicians.

PE Dx was implemented in the ED of UWHC in December'2018. We are extending our research to evaluate the implementation and use of PE Dx; this will provide invaluable lessons to complement what we learned in this study.

4.2 Implications

The processes of VTE prophylaxis for hospitalized patients and of VTE diagnosis for ED patients are complex as they involve multiple team members, occur over time, and rely on various sources of information. Our study clearly shows the need for a human factors approach that goes beyond the technology and examines other aspects of the work system (e.g. team members, tasks, organization, physical environment). Such a sociotechnical systems approach is critical for designing and implementing usable and safe health information technologies such as CDS.

Our study shows the need for multiple approaches and methods for collecting and analyzing data in order to develop a deep understanding of complex patient care processes, such as VTE prophylaxis and VTE diagnosis. We developed and used various methods, including interview, focus group, observation, and survey. These various data collection methods were used in complement with multiple data analysis methods, including role network analysis, survey data analysis, content analysis, cross-case analysis, and design sessions. Our approaches benefited from the multiple disciplines represented in our research team: human factors and systems engineering, patient safety, emergency medicine, critical care medicine, hospital medicine, nursing, and data analytics.

4.3 Study Limitations

This study had several limitations. First, the study took place in only four hospitals and only on certain services and units in these hospitals, which limits the generalizability of the results. On the other hand, the four participating hospitals were diverse (one urban academic center, one rural teaching hospital, and two urban non-teaching hospitals). Although data collection involved a limited number of services and units, we included services and units with patients for whom VTE prophylaxis is an important issue (hospitalist and critical care). Second, we conducted interviews and administered surveys among a sample of clinicians; therefore, limiting the generalizability of the results. We conducted more than 66 hours of observations, interviewed 47 providers, and surveyed 881 clinicians. This extensive data collection was complemented with

input and feedback from multiple experts; therefore, providing additional confidence for the trustworthiness of our results and conclusions.

5. List of Publications and Products

The website of the project can be found at: https://cqpi.wisc.edu/research/health-care-and-patient-safety-seips/vte-and-health-it/. The website provides access to our various data collection tools and a list of publications and presentations.

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